

**No. 31015/89/2016-PI.I**  
**GOVERNMENT OF INDIA**  
**MINISTRY OF CHEMICALS & FERTILIZERS**  
**DEPARTMENT OF PHARMACEUTICALS**

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**A- Wing, Shastri Bhawan,  
New Delhi 110 001**

**Subject: Review application of M/s Sanofi India Limited against price fixation of Enoxaparin 40mg/0.4ml and Enoxaparin 60mg/0.6ml vide NPPA order No. S.O. 2963(E) dated 15.09.2016 issued under Drugs (Prices Control) Order, 2013 (DPCO 2013).**

**Ref: 1) Review application dated 26.09.2016  
2) NPPA notification under review S.O. 2963(E) dated 15.09.2016**

1. This is a petition under paragraph 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) filed by M/s Sanofi India Limited (hereinafter called the petitioner) against notification S.O. No.2963(E) dated 15.09.2016 issued by the National Pharmaceutical Pricing Authority (hereinafter called the NPPA) fixing the ceiling price of Enoxaparin 40mg/0.4ml and Enoxaparin 60mg/0.6ml.

2. The petitioner has contended as under:-

I. The ceiling prices for the above product have been fixed by considering the PTR of August 2015 and applying the WPI decrease of 2.7105% as per the annual wholesale price index (WPI) for preceding calendar year.

II. The price fixation of the above formulations are not in consonance with the NPPP 2012 and the relevant provisions of the DPCO 2013.

III. Paragraph 4 (xi) of NPPP 2012 prescribing the principles for drug price control states as follows "Revision of Ceiling Prices on the basis of MAT value would be carried out only once in five years or as and when NLEM is updated/revised. However, the Government will revise the ceiling price of a medicine under NLEM, if there is a significant change in the market structure of the particular medicine even in between 5 years."

IV. From the above the intent of the Government is very clear that:-

(a) Ceiling price of every Scheduled Formulation needs to be fixed when it is included in Schedule I.

(b) Once ceiling price is so fixed, it will be valid for 5 years, subject to increase or decrease due to change in WPI.

(c) If any new formulation is added to the Schedule during the 5 years, only ceiling price of such scheduled formulation need to be fixed while the ceiling price of other scheduled formulations whose ceiling price was

already fixed would not need to be re-fixed on the basis of MAT until expiry of 5 years.

(d) During the 5 years, if there is a significant change in the market structure, the ceiling price needs to be re-fixed.

V. The price of the above product was fixed for the first time under DPCO 2013 as follows:-

S.O. No. 2246(E) dated 22.7.2013 for Enoxaparin 40mg/0.4ml

S.O. No. 1917(E) dated 28.6.2013 for Enoxaparin 60mg/0.6ml in accordance with Para 4 calculating the Average Price to Retailer on the basis of moving annual turnover for this medicine. They submitted that the price under Para 18(i) on the basis of MAT can only be fixed after 5 years i.e. after 14.6.2018.

VI. Para 18 (1) of DPCO 2013 reads as follows:-

The revision of ceiling prices on the basis of moving annual turnover value shall be carried out -

(a) as and when the National List of Essential Medicines is revised by the Ministry of Health and Family Welfare or five years from the date of fixing the ceiling price under this Order whichever is earlier;

The phrase “whichever is earlier” in Para 18(i) when applied for re-fixing the ceiling prices formulations whose ceiling prices has already been fixed under DPCO, 2013 before the expiry of 5 years, would be clearly against the intent of the NPPP 2012 . There cannot be any rationale to re-fix the ceiling price of any scheduled formulation for the mere reason that some other formulation has been added or deleted from the Schedule I. This can also lead to huge price instability for such scheduled formulations, as the prices of any scheduled formulation would get affected whenever any other formulation gets added to the schedule. Obviously such instability and unpredictability cannot be the intent of NPPP 2012, whose stated objective is to ensure availability of essential medicines at reasonable prices even while providing sufficient opportunity for innovation and competition to support the growth of industry, thereby meeting the goals of employment and shared economic wellbeing for all.

VII. Once the Ceiling price has been fixed under DPCO 2013, the revision on the basis of MAT for the same formulation can be done only once in five years

VIII. The ceiling price for the medicines added in the first schedule on the basis of amendments or revision, if required, in the first schedule are required to be notified and fixed as per the provisions of Para 17 of the DPCO 2013 within a period of sixty days from the date of the notification amending the First Schedule. Accordingly, the provisions of Para 17 are only to be made applicable when NLEM has been updated/revised vide SO 701(E) dated 10.3.2016 as per the intention in para 4(xi) NPPP 2012. Thus, on a harmonious construction and a rational interpretation, the phrase “whichever is earlier” appearing in para 18(1) can only mean that it would permit:-

- (a) fixing ceiling price of formulations which are newly added to the Schedule I as and when they are added and
  - (b) re-fixing the ceiling prices of those scheduled formulations, whose ceiling prices have already been fixed under DPCO, 2013 only after lapse of 5 years from the date of fixing its ceiling price.
  
- IX. Secondly, it may be seen from the Working Sheet Related to Price Notified on 15<sup>th</sup> September, 2016 regarding Enoxaparin Injection 40mg and 60 mg that Computation of Ceiling price has been done under Para 4 of DPCO 2013 taking into account of WPI Reduction w.e.f. 1.4.2016 @ -2.7105%.
  
- X. Without prejudice to their contention that ceiling price for the above formulation ought not to have been fixed under para 18(1), the petitioner company state that the reduction of 2.7105% is not in accordance with provision of para 9(5), which reads as follows
  - (a) "The market based data for fixing the ceiling price of a scheduled formulation due to a revision in the first schedule shall be the data available for the month ending immediately before six month of notification of revision in the first schedule".
  
- XI. At the time of fixation of ceiling price, DPCO 2013 merely requires computation of Simple Average of Prices prevailing six months prior to the date of price fixation and nowhere does it require the same to be reduced by WPI reduction of the preceding calendar year. Thus for all price fixations, the data prior to six months of the price notification ought to have been taken without reduction of 2.7105%, being the WPI change for calendar year 2015.
  
- XII. In view of the position as explained above, there is no justification for price fixation of regarding Enoxaparin Injection 40mg and 60 mg on MAT basis and also considering the WPI decrease for calendar year 2015 which is against the NPPP 2012 and the provisions of the DPCO 2013. They requested that the ceiling price of regarding Enoxaparin Injection 40mg and 60 mg. notified vide SO 2963(E) dated 15.09.2016 may be withdrawn immediately.
  
- XIII. They also confirmed that as required under para 31 they have implemented the ceiling price notified under SO 2963(E) dated 15.09.2016 before filing the Review Application and they also attach a copy of the relevant Form V.
  
- 3. Comments of NPPA:
  - (i) For Enoxaparin 40mg, NPPA has fixed the ceiling price of Rs. 439.39 per pack vide S.O 2246(E) dated 22.7.2013 and the same was revised to Rs. 467.16, Rs. 485.14 & Rs. 471.99 per pack vide S.O. 1156(E), 619(E) & 644(E) dated 28.4.2014, 26.02.2015 & 02.3.2016 respectively. Ceiling price for Enoxaparin 60mg was fixed Rs. 534.98 per pack vide S.O. 1917(E) dated 28.6.2013 and the same was revised to Rs. 564.54, Rs. 586.27 & Rs. 570.38 per pack vide S.O. 1156(E), 619(E) & 644(E) dated 28.4.2014, 26.02.2015 & 02.3.2016 respectively under NLEM 2011.

- (ii) The ceiling price of Rs. 90.454 per 0.1ml for Enoxaparin 40mg/0.4ml as well as Enoxaparin 60mg/0.6ml, was notified vide S.O. 2963(E) dated 15.9.2016 under para 4, 10, 11 14, 16, 17 & 18 of DPCO 2013 under para 18 of DPCO, 2013, as the NLEM 2011 was substituted by NLEM 2015. Para 18 of DPCO 2013 states that “the revision of ceiling prices of medicines on the basis of moving annual turnover is done as and when the National List of Essential Medicines is revised by Ministry of Health & Family Welfare or 5 years from the date of fixing the ceiling price under this order whichever is earlier”. Therefore, ceiling prices of above formulations have been revised under para 18 of DPCO, 2013 as per the provisions of DPCO.2013.
- (iii) Further, a similar case [Dr. Reddy’s Laboratories vs UoI & others (WP/C 5392/2016)], where the petitioner company had raised similar contentions regarding para 18(i), the Hon’ble Division bench of High Court of Delhi on 25<sup>th</sup> July 2016 has dismissed the stay application filed by the company against NPPA’s price notification.

4. Examination:

The representative of the petitioner did not attend the personal hearing. Hence, the proceeding was held ex-parte decision based on written submission in the review petition.

The petitioner company has challenged the NPPA Order S.O. 2963(E) dated 15/09/2016 for price fixation of their formulations listed therein. The main contentions of the petitioner company are as under:

- a. The revision of ceiling price of those drugs whose prices had already been fixed, should not be fixed again before the expiry of 5 years from the date of original fixation of the ceiling price.
- b. The ceiling prices should not be fixed by taking basis PTR August, 2015 by deducting negative WPI as applicable as on 1<sup>st</sup> April, 2016.

Para 18(i) of DPCO 2013 clearly states that the revision of ceiling prices on the basis of moving annual turnover value shall be carried out “as and when the National List of Essential Medicines is revised by the Ministry of Health and Family Welfare or five years from the date of fixing the ceiling price under this Order whichever is earlier.” In view of this, NPPA has revised the ceiling prices of the formulations strictly as per the provision of DPCO 2013.

As regards the other point that negative WPI should not be taken while fixing the ceiling price vide notification dated 15.9.2016, since the drugs are not new drugs in NLEM 2015, the WPI impact has to be taken care of while fixing the ceiling prices. Therefore, the petitioner company has no merit in the petition and may be rejected.

5. Government Decision:

**“The issues raised by the petitioner company in the review petition have no merit and hence the review petition is hereby rejected.”**

Issued on this date, the 14<sup>th</sup> day of February, 2017.

**(Jai Priye Prakash)**  
**Secretary**  
**For and on behalf of the President of India**

To

1. M/s. Sanofi India Limited  
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2. The Member Secretary,  
National Pharmaceutical Pricing Authority,  
YMCA Cultural Centre Building, New Delhi-110001

Copy to :

1. PS to Hon'ble Minister (C&F), Shastri Bhawan, New Delhi for information.
2. T.D., NIC for uploading the order on Department's Website